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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/069,405	05/29/2002	Jean-Pierre Benoit	03715.0110	3630

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EXAMINER

TRAN, THAO T

ART UNIT PAPER NUMBER

1711

DATE MAILED: 07/28/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

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<b>Office Action Summary</b>	Application No. 10/069,405	Applicant(s) BENOIT ET AL.	
	Examiner Thao T. Tran	Art Unit 1711	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 11 May 2006.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1,3-21 and 25-41 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,3-21 and 25-41 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

1. This is in response to the Amendment and Affidavit filed on 5/11/2006. The Amendment filed on 12/19/2005 has also been entered and acknowledged.
2. Claims 1, 3-21, and 25-41 are currently pending in this application. Claims 1 and 3 have been amended. Claim 41 has been newly added.
3. In view of the prior Office action of 12/13/2005, the 112 rejection of claim 3 has been withdrawn due to the Amendment made thereto.
4. The prior art rejections of the claims are maintained as follows.

### ***Claim Rejections - 35 USC § 102***

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1, 3-21, 25-31, and 33-41 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 95/13799.

WO '799 teaches a process for microencapsulating an active agent by coacervation, the process consisting of dissolving a polymer in an organic solvent, which contains the active substance; mixing the polymer/active agent solution (first phase) with another liquid (second phase) to form microdroplets of the active agent encapsulated in the polymer; quenching the mixture at 0-4°C with water or an aqueous solution (see Figures 1-3; page 9, 3<sup>rd</sup> paragraph; page 15, 2<sup>nd</sup> & 3<sup>rd</sup> paragraphs). WO '799 further discloses the organic solvent comprises ethyl acetate

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and an alcohol or a ketone of 1 to 3 carbon atoms, which include ethanol and propanol, meeting the requirement of the non-solvent in claims 1 and 41. The quenching solution contains water or an aqueous solution, meeting the requirement for the curing agent in claims 1 and 41. The second phase liquid and the quenching solution contain a surfactant, polyvinyl alcohol. (See page 22, last paragraph to page 23, 1<sup>st</sup> paragraph; page 26, 2<sup>nd</sup> paragraph; claims 1-49). The stirring is at a speed of 700 rpm and the particle size is 25 microns (see page 55, 1<sup>st</sup> paragraph; page 59, Example 15).

It is noted that since WO '799 uses the same organic solvent, non-solvent, and curing agent as presently claimed, the composition of the reference would inherently have the same properties and characteristics, such as dissolution or miscibility as the claimed invention. The solvents as indicated above in WO '799 are also non-chlorinated.

With respect to the concentration of the surfactant in the curing agent, WO '799 teaches a concentration of 01 to 10 wt% (see page 19, 1<sup>st</sup> paragraph), which appears to read on the instantly claimed ranges. WO '799 further teaches the polymer having a weight-average molecular mass of between 10,000 and 90,000 g/mol (see page 17, 1<sup>st</sup> paragraph).

WO '799 further teaches the polymer to be 75:25 PLGA (see page 16, ln. 24; page 35, ln. 7-8). Although the reference does not specifically teach the polydispersity index or the relative dielectric permittivity, since the reference teaches the same polymer, the reference's polymer would inherently have the same properties as those of the presently claimed invention.

***Claim Rejections - 35 USC § 103***

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claim 32 is rejected under 35 U.S.C. 103(a) as being unpatentable over WO '799 as applied to claims 1 and 10 above.

WO '799 is as set forth in claims 1 and 10 above and incorporated herein.

WO '799 further teaches that the solvent system is optimal at 0-4°C (see page 28, ln. 13).

Therefore, although the reference does not teach the coacervation temperature being equal to -4°C, it would have been obvious to one of ordinary skill in the art, at the time the invention was made, that the coacervation temperature would have been adjusted to -4°C in order to bring forth maximal benefits attendant therewith. This is because Applicants have not disclosed the advantages of this temperature over other temperatures. And since WO '799 teaches that the coacervation temperature would be optimal at 0-4°C, the coacervation temperature taught by WO '799 would also include temperatures outside 0-4°C.

***Response to Arguments***

9. Applicant's arguments filed 5/11/2006 have been fully considered but they are not persuasive. A major part of the following response is reiterated from the response presented in the Office action of 12/13/2005.

With respect to Applicants' arguments that the presently claimed invention does not use any chlorinated solvent, it is first noted that the claim language in claim 1 does not include this limitation. It is further noted that the invention of WO '799 uses both chlorinated and non-chlorinated solvents, thus embracing the presently claimed invention.

With respect to Applicants' arguments that the invention of WO '799 uses the organic solvent and the non-solvent that are immiscible, it is noted that since the reference discloses the use of ethyl acetate and an alcohol having 1 to 3 carbon atoms, the solutions of the reference would inherently have the same properties or characteristics, such as solubility or miscibility, as those in the presently claimed invention.

Applicants further contend that WO '799 teaches the non-solvent as silicone oil, but not an alcohol. While it is true that WO '799 teaches the use of silicone oil as a non-solvent, the reference also teaches a solvent blend including at least two of the following: an ester, an alcohol, and a ketone; wherein the alcohols have a general formula of  $R_3CH_2OH$ , with  $R_3$  selected from the group consisting of hydrogen or alkyl of from 1 to 3 carbon atoms (see page 15, 3<sup>rd</sup> paragraph). The alcohol thus comprises ethanol and propanol as presently claimed. WO '799 also uses water and/or an aqueous solution in the second phase and as a quenching liquid. The use of an alcohol having 1 to 3 carbon atoms and water in the second phase would meet the requirement of the non-solvent and curing agent in the instantly claimed invention.

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Therefore, WO '799 anticipates the presently claimed invention.

10. The Affidavit filed on 5/11/2006 shows the WO '799 process as a solvent extraction and not the same as presently claimed. However, it is noted that all the steps as presently claimed are included in the reference. Thus, the reference anticipates the claimed invention.

11. In summary, Applicant's arguments do not comply with 37 CFR 1.111(c) because they do not clearly point out the patentable novelty which he or she thinks the claims present in view of the state of the art disclosed by the references cited or the objections made. Further, they do not show how the amendments avoid such references or objections.

### ***Conclusion***

12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Thao T. Tran whose telephone number is 571-272-1080. The examiner can normally be reached on Monday-Friday, from 9:00 a.m. - 5:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Seidleck can be reached on 571-272-1078. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Thao T. Tran  
Primary Examiner  
Art Unit 1711

tt  
July 24, 2006